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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,079	07/11/2006	James Knox Russell	PHUS040020US2	6955

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EXAMINER	
LAVERT, NICOLE F	

ART UNIT	PAPER NUMBER
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,079	RUSSELL ET AL.	
	Examiner	Art Unit	
	NICOLE F. LAVERT	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,15,17,24-30 and 34* is/are pending in the application.

4a) Of the above claim(s) *18,19,21-23 and 31-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,15,17,24-30 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/11/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Claims 18-19, 21-23 & 31-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 29 May 2008. The Applicant argues that the restriction requirement between the method and apparatus claims is improper, because the independent claim 18 is still of the same scope as it was when it was searched, considered and the non-final Office Action was issued on 14 November 2007. In addition to the above arguments, the Applicant also argues that the restriction between the apparatus and the method is improper because the apparatus of claim 34 cannot be used by a materially different method than that of claim 23 and the method of claim 23 cannot be performed with a materially different apparatus than the apparatus of claim 34. The Examiner disagrees with the above arguments. The claims have been amended and therefore are not of the same scope and further points out that it has been found a burden exists between the method and apparatus claims since the apparatus as claimed can be used by a materially different process such as a method of stimulating the heart in order to treat tachyarrhythmia versus a method for communicating information about a patient, in which is instantly claimed, including the apparatus of claim 34, as argued. Therefore, the Examiner withdraws the method claims as stated above. The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-4, 6, 8-12, 15, 17, 24-30 & 34** are rejected under 35 U.S.C. 102(b) as being anticipated by Nolan et al. (US 5,404,877).

For **claim 1**, Nolan et al. discloses, a physiological monitoring system which comprises (col 1, ln 8-15): at least one sensor for detecting a biological signal, representative of a physiological characteristic of a monitor-wearing patient and generating an electrical signal representative of the biological signal (col 3, ln 28-44); at least one sensor for detecting the physical activity of the patient and generating an electrical signal, representative of physical activity (col 4, ln 16-19); processing means, coupled to said sensors for processing said electrical signals [(col 5, ln 50-62), (col 8, ln 49-54) & (Fig 1, 28)]; an activity threshold detector coupled to said processing means for receiving said electrical signals representative of physical activity [(col 3, ln 32-44) & (col 4, ln16-19)]; a user interface for communicating information about the detected biological signal to the patient (col 9, ln 10-22); means for adaptively controlling the communication of the information about the detected biological signal in accordance with a level of the sensed physical activity as determined by said activity threshold detector [(col 3, ln 32-44), (col 4, ln 16-19) & (col 9, ln 23-39)].

In regards to **claim 2**, Nolan et al. discloses, the system of claim 1 (col 1, lines 8-15), further comprising a means for programming said physical activity sensor for operational control at a selected threshold of physical activity (col 4, lines 16-19).

In regards to **claim 3**, Nolan et al. discloses, the system of claim 1 (col 1, lines 8-15), wherein the biological signal sensor is adapted to sense cardiac signals (col 3, lines 28-44).

In regards to **claim 4**, Nolan et al. discloses, the system of claim 1 (col 1, lines 8-15), wherein the biological signal sensor (col 3, lines 28-44) comprises electrocardiography electrodes that detect biological signals representative of the heart beats of the patient (col 2, lines 9-14).

In regards to **claim 6**, Nolan et al. discloses, the system of claim 1 (col 1, lines 8-15), wherein the physical activity sensor (col 4, lines 16-19) comprises an accelerometer, a pedometer, an electrical noise detector, electronic capacitive sensor, an electromyographic sensor, a skin impedance sensor [(col 3, lines 45-49) & (col 4, lines 51-53)], or a piezoelectric sensor.

In regards to **claim 8**, Nolan et al. discloses, the system of claim 1 (col 1, lines 8-15), further comprising a means for wireless transmission of information about the detected biological signal or system functions to a receiver external to the system (col 9, lines 23-39).

In regards to **claim 9**, Nolan et al. discloses, the system of claim 1 (col 1, ln 8-15), wherein the at least one sensor comprises at a or more electrocardiography electrodes that sense electrocardiography signals from a patient (col 2, lines 9-14), whereby the electrocardiography and physical activity sensors generate electrical signals representative of each respective biological signal (col 3, lines 28-44); wherein the processing means an arrhythmia threshold detector coupled to the electrocardiography sensor [(col 5, lines 54-60) & (Fig 1, 28)] for receiving said electrical signals representative of the electrocardiography signals and determining whether the signals are below or above a preset threshold (col 3, lines 60-66); wherein the activity threshold detector coupled to the activity sensor for receiving said electrical signals representative of the activity level of the patient and determining whether the signals are below

or above a predetermined threshold [(col 3, lines 60-66) & (col 4, lines 16-19)]; further including a system error detector for detecting system errors and determining if the error meets pre-determined criteria (col 9, lines 4-22); the means for adaptively controlling the communication includes a processor for controlling the communication of system and biological signal information to the patient [(col 5, lines 50-62) & (col 8, lines 48-50)] through a user interface (col 9, lines 10-22) based on the detection of an activity threshold by said activity threshold detector [(col 3, lines 60-66) & (col 4, lines 16-19)], arrhythmia threshold by said arrhythmia threshold detector (col 5, lines 54-60), and/or system errors by the system error detector (col 9, lines 4-22).

In regards to **claim 10**, Nolan et al. discloses, the system of claim 9 (col 1, lines 8-15), wherein the user interface comprises an alarm circuit comprising acoustic, tactile, or visual modes of communicating information to the patient (col 9, lines 10-22), and mode is determined by processor based on whether the signals from the respective detectors meet pre-determined thresholds [(col 3, lines 60-66) & (col 8, lines 48-50)].

In regards to **claim 11**, Nolan et al. discloses, the system of claim 9 (col 1, lines 8-15), wherein processor further comprises a calibration means (col 9, lines 40-54) for setting the threshold of the arrhythmia threshold detector (col 5, lines 50-62) based on processing of electrocardiography signals from the patient to generate a baseline of electrocardiography information [(col 8, lines 48-62) & (col 9, lines 40-54)].

In regards to **claim 12**, Nolan et al. discloses, the system of claim 9 (col 1, lines 8-15), further including: a memory component (col 8, ln 50-63), the processor saving the electrocardiography signals into the memory component such that electrode signals below the

preset threshold of the arrhythmia threshold detector are overwritten and electrocardiography signals above the pre-set threshold are saved in the memory component [(col 3, ln 60-66), (col 5, ln 50-62) & (Fig 1, 28)].

In regards to **claim 17**, Nolan et al. discloses, the system of claim 9 (col 1, lines 8-15), further comprising means of wireless communication to an external system, for communication of information about the patient and system state to the patient or to others (col 9, lines 23-39).

For **claim 24**, Nolan et al. discloses, a physiological monitoring system comprising (col 1, lines 8-15): at least one sensor for detecting a biological signal of a patient (col 3, lines 28-44); at least one sensor for detecting physical activity of the patient (col 4, lines 16-19); a processor coupled to the sensors the processor including: a biological signal processor for comparing the detected biological signal with biological signal threshold data (col 8, lines 50-63) and generating a biological signal alarm condition if the threshold is met (col 5, lines 50-62); and an activity threshold detector for processing the electrical signals representative of physical activity to determine physical activity of the patient [(col 3, ln 32-44) & (col 4, ln 16-19)], an adaptive communication controller which determines alarm states based on the biological signal alarm condition and the determined physical activity (col 9, ln 10-21) a user interface controlled by the processor adaptive communication controller to produce at least two different types of alarms [(col 7, ln 45-51) & (col 9, lines 10-22)] based on the biological signal alarm condition and the physical activity of the patient [(col 3, lines 49-59) & (col 4, lines 16-19)].

In regards to **claim 25**, Nolan et al. discloses, the physiological monitoring system of claim 24 (col 1, lines 8-15) a system monitor which detects system malfunctions and classifies the detected malfunctions as critical or non-critical; and wherein the user interface further bases

the alarm type on any detected system malfunctions [(col 7, ln 45-51) & (col 9, lines 10-22)]. Note that the analyzer as disclosed by Nolan et al. has the capabilities of classifying the detected malfunctions as instantly claimed due to the analyzer communicating to the alarm if a malfunction exists (col 9, ln 10-22).

In regards to **claim 26**, Nolan et al. discloses, the physiological monitoring system of claim 24 (col 1, lines 8-15) wherein the processor determines from detected biological signal and the detected physical signal whether the patient is unconscious, and wherein the user interface sends an emergency response alarm to a remote third party responder to determining the patient is unconscious [(col 4, ln 1-15) & (col 7, ln 45-51)].

In regards to **claim 27**, Nolan et al. discloses, the physiological monitoring system of claim 1 (col 1, lines 8-15) wherein the activity threshold detector determines when the patient is at rest or active, and further including: a means for determining when the information about the detected biological signal is urgent or non-urgent (col 3, ln 28-59).

In regards to **claim 28**, Nolan et al. discloses, the physiological monitoring system of claim 27 (col 1, lines 8-15) wherein the means for adaptively controlling the communication of the information further: in response to the information being urgent, communicates the information of the patient; in response to the information being non-urgent and the patient being at rest, inhibits the communication of the information of the patient; in response to the information being non-urgent and the patient being active, communicates the information to the patient [(col 3, ln 28-59), (col 4, ln 16-50) & (col 9, ln 1-54)].

In regards to **claim 29**, Nolan et al. discloses, the physiological monitoring system of claim 27 (col 1, lines 8-15) a means for determining when the detected biological information

signal is inconsistent with the level of physiological activity; and wherein the means for adaptively controlling the information inhibits the communication of the information about the detailed biological signal when the means for determining when the detected biological information signal is inconsistent with the level of physiological activity determines that biological information signal is inconsistent with the level of physiological activity [(col 3, ln 20-44) & (col 4, ln 16-50)].

In regards to **claim 30**, Nolan et al. discloses, the physiological monitoring system of claim 9 (col 1, lines 8-15) wherein the activity threshold detector determines when the patient is at least at rest and active, and wherein the processor determines when the information is at least urgent and non-urgent; and wherein the processor adaptively communicates and inhibits the communication of the information in accordance with whether the patient is at rest or active and whether the information is urgent or non-urgent [(col 3, ln 28-59), (col 9, ln 1-54)].

For **claim 34**, Nolan et al. discloses, an apparatus for communicating information about a patient during ambulatory monitoring of a physiological condition of the patient comprising [(col 1, ln 8-15) & (col 2, ln 21-25)]: a physiological monitoring system for attachment to a patient; means for detecting a selected physiological parameter of the patient with the physiological monitoring system (col 3, ln 28-44); means for sensing physical activity of the patient (col 4, ln 16-19); means for comparing the detected physiological parameter with a first pre-determined criteria to determine a physiological state of the patient reflecting an alarm condition [(col 3, ln 32-44), (col 4, ln 16-19) & (Fig 1, 28)]; means for generating an alert signal if the physiological condition of the patient reflects an alarm condition; means for transmitting the alert signal to the patient if the sensed physical activity of the patient indicates the patient is active and inhibiting

the transmission of the alert signal if the sensed physical activity of the patient indicates that the patient is at rest [(col 3, ln 28-59) & (col 9, ln 1-54)].

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. **Claims 5, 7, 13 & 15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nolan et al. (US 5,404, 877) in view of Toda et al. (US 20020036446).

Nolan et al. shows all of the features of the instantly claimed invention as discussed above.

Nolan et al. fails to disclose a physical activity sensor comprising a transducer including a piezoelectric element.

Toda et al. teaches a piezoelectric transducer with a piezoelectric polymer provided with electrodes on its surface [0001].

It would have been obvious to one of ordinary skill in the sensor art to have modified Nolan et al. with the use of a piezoelectric transducer, as taught by Toda et al., in order to

provide predictable results pertaining to providing a source of an effective excitation of acoustic energy so as to provide an acoustic feedback signal [Toda, 0001].

Response to Arguments

3. Applicant's arguments filed 29 May 2008 have been fully considered but they are not persuasive.

The Applicant argues that claims 1 & 30, calls for a means for adaptively controlling the communication of information about the detected biological and system functions in accordance with a level of the sensed activity as determined by the activity threshold detector, in which is not anticipated by Nolan et al. The Examiner disagrees with the argument and further points out that Nolan et al. discloses an alarm that may receive from an external device control information used to govern data acquisition by the alarm, in which the alarm may initiate communication with an external device and warn of abnormal physiological conditions and malfunctions of a device (col 9, ln 1-22).

The Applicant also argues that Nolan et al. fails to disclose an activity threshold or an adjustable threshold. The Examiner also disagrees with this argument and further points out that Nolan et al. discloses a metabolic demand indication used to determine heart rate thresholds in which a warning signal is generated based on if a measured heart rate and if the measured heart rate exceeds an automatically determined threshold heart rate derived forma physiological sensor measurement (col 3, ln 39-44 & 60-66).

In addition to the above arguments, the Applicant also argues that Nolan et al. fails to disclose electrocardiography electrodes that detect biological signals representative of the heart beats of a patient and that the combination of the Toda et al. reference does not provide an

enabling disclosure of how to convert the impedance monitor of Nolan et al. into a passive piezoelectic based monitor in regards to claims 4 & 7. The Examiner disagrees with the above arguments and further points out that Nolan et al. discloses electrode leads for sensing ECG signals (Nolan, col 2, ln 9-14). In response to the argument directed towards claim 7, the Examiner notes that the Nolan et al. in view of Toda et al. shows that it is obvious to one of ordinary skill in the sensor art to have modified Nolan et al. with the use of a piezoelectric transducer, as taught by Toda et al., in order to provide predictable results pertaining to providing a source of an effective excitation of acoustic energy so as to provide an acoustic feedback signal [Toda, 0001].

Further arguments by the Applicant include: Nolan et al. fails to disclose a calibration means for setting a threshold of an arrhythmia threshold detector and a memory component in which signals are overwritten if they a below an arrhythmia threshold and saved if they are above it. The Examiner disagrees and further points out that the controller disclosed by Nolan et al. incorporates calibrating techniques such as disconnecting power to the communication circuitry in order to detect and analyze data consisting of predetermined physiological conditions or operations (col 9, ln 40-54). In regards to a memory component, the controller disclosed by Nolan et al. contains memory reading and writing functions in which is used to activate a warning signal based on if a heart rate exceeds a programmed maximum rate if when the measured heart rate exceeds an automatically-determined threshold heart rate derived from a physiological sensor measurement coupled to the controller [(col 3, ln 60-66), (col 8, ln 45-63) & (Fig 1, 28)].

4. Applicant's arguments, filed 29 May 2008, with respect to 35 U.S.C. 112, second paragraph have been fully considered and are persuasive. The 112, second paragraph rejections of the claims has been withdrawn.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. LAVERT whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (Alt. Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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